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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,577	11/13/2003	Stefan Berg	1103326-0525 DIV	1754
7470	7590	10/29/2004	EXAMINER	
WHITE & CASE LLP PATENT DEPARTMENT 1155 AVENUE OF THE AMERICAS NEW YORK, NY 10036			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 10/714,577	Applicant(s) BERG ET AL.	
	Examiner Rita J. Desai	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-10,12,13 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6, 7-10, 12,13, 25-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/26/04</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Priority

The priority to US 09/171,570 and 10/285,743 and PCT /SE98/01603 has been noted.

Claims 1, 2, 4, 6, 7-10, 12,13, 25-30.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for R4 and R5 being a hetero ring such as morphini, piperazine diazepin and piperidino, does not reasonably provide enablement for them being hetero ring s with other hetero atoms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

There are several criteria required to meet the scope of enablement standard.

The scope of the claims R3 and R4 are overly broad and there is no description in the specifications as to what generically recited “5, 6 or 7 membered heterocyclic rings containing one or 2 hetero atoms selected from N, O, S ” are. The specifications do not provide any guidance as to which groups are included. The groups that are described are provisoed out in the

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claims! Hence the specifications have a description of the heterocyclic groups that are NOT claimed. The compounds are used to treat diseases and hence they are highly specific since drugs work in a lock and key mechanism, thus one would require an undue amount of experimentation to make and use the compounds of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite that R3 substituents are heterocyclic are 5, 6 or 7 membered heterocyclic rings containing one or 2 hetero atoms selected from N, O, S, and it is not clear which groups the applicants actually mean.

Claims 13, 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim 13, 27 recites treatment of 5-hydroxytryptamine-mediated disorder.. This is *a reach through claim* since it describes a mechanism and hence would include any disease which would later be discovered to be treatable by the same mechanism.

Applicants can overcome this by inserting the specific diseases in the claim.

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The claims 25, 26, 28 also have a laundry list of diseases disclosed and drugs do not have a umbrella efficacy of treating the several diseases .

Applicants can overcome this by limiting it to one type of disease.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

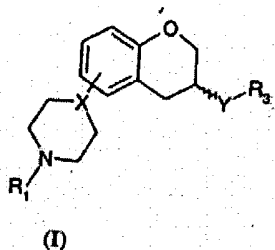
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 6, 7-10, 12,13, 25-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6479497. Although the conflicting claims are not identical, they are not patentably distinct from each other because they generically claim the compounds and compositions of the same genus. Applicants compounds are drawn to the formula

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1. (currently amended) A compound ~~having the~~ of formula (I)



wherein

X is N ~~or CH~~;

Y is NR_2CH_2 , CH_2NR_2 , NR_2CO , CONR_2 , NR_2SO_2 or NR_2CONR_2

wherein R_2 is H or $\text{C}_1\text{-C}_6$ alkyl;

R_1 is H, $\text{C}_1\text{-C}_6$ alkyl or $\text{C}_3\text{-C}_6$ cycloalkyl;

R_3 is $\text{C}_1\text{-C}_6$ alkyl, $\text{C}_3\text{-C}_6$ cycloalkyl or $(\text{CH}_2)_n\text{-aryl}$,

~~wherein aryl is phenyl or a heteroaromatic ring~~

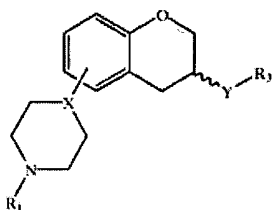
~~containing one or two heteroatoms selected from N, O and~~

~~S and which~~ $(\text{CH}_2)_n\text{-phenyl}$, wherein the phenyl may be

and the US 6479497 is drawn to

which is defined as:

1. A compound of formula (I)



wherein

X is N;

Y is CH_2NR_2 , NR_2CO , CONR_2 , NR_2SO_2 or N

wherein R_2 is H or $\text{C}_1\text{-C}_6$ alkyl;

R_1 is H or $\text{C}_1\text{-C}_6$ alkyl;

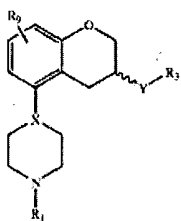
R_3 is $(\text{CH}_2)_n\text{-phenyl}$,

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Thus even though some of the substituents are different they are drawn to the generally the same genus and process of making.

Claims 1, 2, 4, 6, 7-10, 12,13, 25-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. US 6387 899. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds composition and method of use are drawn to compounds of a larger scope which include the compounds of the invention. See below.

1. A compound of the formula I



wherein

X is N or CH;

Y is CH₂-NR₂, NR₂-CO, CO-NR₂ or NR₂SO₂, wherein

R₂ is H or C₁-C₆ alkyl;

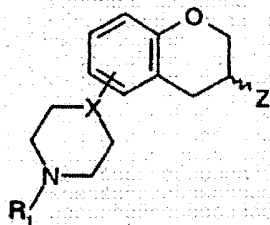
R₁ is H, C₁-C₆ alkyl or C₃-C₆ cycloalkyl;

R₃ is C₁-C₆ alkyl, C₃-C₆ cycloalkyl or (CH₂)_n-aromatic ring, wherein the aromatic ring is phenyl or a heteroaromatic ring containing one or two heteroatoms selected

Claim 30 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6384 225 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the same intermediate with X being a N is clearly taught.

Applicants claim is

30. (currently amended) A compound having of the formula.



wherein

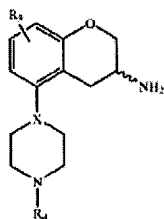
$$X=N \text{ or } CH_3;$$

Z=NH₂ or COOH; and

R₁ is H, C₁-C₆ alkyl or C₃-C₆ cycloalkyl.

and US 6384225 teaches

2. A compound of the formula



wherein

X is N;

R₀ is C₁-C₈ alkyl, C₃-C₆ cycloalkyl, OCF₃, OCHF₂, OCH₂F, halogen, CN, CF₃, OH, C₁-C₆ alkoxy, C₁-C₆

[illegible]

The difference is in the R9 which is not a hydrogen.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Since these compounds are intermediates and are used to prepare the same compounds ,

in the presence of unexpected results the compounds with and alkyl instead of a H are

considered obvious.

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Conclusion

The claims are hence not found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai
Primary Examiner
Art Unit 1625

RJ Desai

10/27/04

R.D.
October 27, 2004